

Claims

1. A single-step immunoassay method for detecting and quantifying contaminant host cell proteins in a recombinant protein sample, the method comprising:
 - a) adding to a recombinant protein sample
 - i) a capture reagent comprising anti-host cell protein antibodies, and
 - ii) a detection reagent comprising anti-host cell protein antibodies;
 - wherein the capture reagent and the detection reagent are added substantially simultaneously; and
 - b) detecting the level of host cell protein in the recombinant protein sample.
2. The method of claim 1, wherein the capture reagent is immobilized.
3. The method of claim 2, wherein the capture reagent is immobilized on a bead.
4. The method of claim 1, wherein the detection reagent further comprises a detectable moiety.
5. The method of claim 1, wherein the detection reagent is detected by adding a secondary antibody that recognizes the detection reagent and wherein said secondary antibody comprises a detectable moiety.
6. The method of claim 1, wherein the anti-host cell protein antibodies are affinity purified.
7. The method of claim 6, wherein the anti-host cell protein antibodies are affinity purified by:
 - a) preparing an affinity medium comprising host cell protein coupled to a support; and
 - b) separating anti-host cell antibodies from other compounds using said affinity medium.
8. The method of claim 1, wherein the detection reagent comprises:
 - a) purified anti-HCP antibodies from either the same or different animal source labeled with a detectable moiety; or
 - b) an anti-HCP IgG fraction from a different animal source than that of the capture reagent anti-HCP antibodies; or
 - c) undiluted, unfractionated serum containing anti-HCP antibodies from a different animal source than that of the capture reagent anti-HCP antibodies.
9. The method of claim 1, wherein the anti-HCP antibodies are produced by immunizing an animal with host cell proteins, and wherein the capture reagent anti-HCP antibodies are produced by immunizing a first animal species and the detection reagent anti-HCP antibodies are produced by immunizing a second animal species.
10. An immunoassay method for detecting and quantifying contaminant host cell proteins in a recombinant protein sample, the method comprising:
 - a) immobilizing a capture reagent comprising anti-host cell protein antibodies; and
 - b) adding to said immobilized capture reagent a recombinant protein sample and a detection reagent comprising anti-host cell protein antibodies, wherein the detection reagent and the recombinant protein sample are added substantially simultaneously.
11. The method of claim 10, wherein the immunoassay is an enzyme-linked immunosorbent assay (ELISA).
12. The method of claim 10, wherein the anti-host cell protein antibody preparation is affinity purified.
13. A reagent for use in a single-step immunoassay method for detecting and quantifying contaminant host cell proteins in a recombinant protein sample, the reagent comprising an affinity purified anti-host cell protein antibody preparation.

14. The reagent of claim 13, wherein the antibody preparation is affinity purified by: preparing an affinity medium comprising host cell proteins coupled to a support; and separating anti-host cell antibodies from other compounds using said affinity medium.
15. The reagent of claim 14, wherein the anti-HCP antibodies are produced by immunizing an animal with host cell proteins, and wherein the reagent anti-HCP antibodies are produced by immunizing two different animal species.
16. The reagent of claim 13, wherein the affinity purified anti-host cell protein antibody preparation is a capture reagent and a detection reagent in an enzyme-linked immunosorbent assay (ELISA).
17. A kit for detecting and quantifying contaminant host cell proteins in a recombinant protein sample as part of an overall assay, the kit comprising:
 - a) a capture reagent comprising an affinity-purified anti-host cell protein antibody preparation; and
 - b) a detection reagent comprising:
 - i) purified anti-host cell protein antibody and a detectable moiety, or
 - ii) a detection reagent comprising unpurified anti-HCP IgG fraction from different animal source than that of the capture reagent anti-HCP antibodies, and a detection labeled secondary antibody to this IgG fraction, or
 - iii) a detection reagent comprising undiluted, unfractionated anti-HCP containing serum from a different animal source than that of the capture reagent anti-HCP antibodies, and a detection labeled secondary antibody to the IgG in the serum.
18. The kit of claim 17, wherein the antibody preparation is affinity purified.
19. The kit of claim 17, wherein the anti-HCP antibodies are produced by immunizing an animal with host cell proteins, and wherein the reagent anti-HCP antibodies are produced by immunizing two different animal species.
20. The kit of claim 17, wherein the capture reagent is immobilized.
21. The kit of claim 20, wherein the kit is an enzyme-linked immunosorbent assay (ELISA).
22. A single-step ELISA assay for detecting and quantifying contaminant host cell proteins in a recombinant protein sample, the method comprising:
 - a) immobilizing an affinity purified capture reagent comprising anti-host cell protein antibodies, and
 - b) adding to said immobilized capture reagent:
 - i) an affinity purified detection reagent comprising anti-host cell protein antibodies and a detectable moiety; and
 - ii) an aliquot of the recombinant protein sample;wherein the detection reagent and the recombinant protein sample are added to the immobilized capture reagent substantially simultaneously; and
 - c) detecting the level of host cell protein in the recombinant protein sample.